510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k050352

B. Purpose for Submission:

Clearance of new device

C. Measurand:

Vaginal pH, Nitrite, Proline iminopeptidase, Blood, Protein and Leukocyte

D. Type of Test:

Qualitative

E. Applicant:

AmeriTek Research, LLC

F. Proprietary and Established Names:

FemLab® Vaginitis test kit

G. Regulatory Information:

1. Regulation section:

   21 CFR § 864.6550, Occult blood test
   21 CFR § 862.1550, Urinary pH (nonquantitative) test system
   Limitation: 21 CFR 862.9 (c), (6) and (9)
   21 CFR § 862.1510, Nitrite (nonquantitative) test system
   Limitation: 21 CFR 862.9 (c), (6) and (9)
   21 CFR § 862.1645, Urinary protein or albumin (nonquantitative) test system
   Limitation: 21 CFR 862.9 (c), (6) and (9)
   21 CFR § 864.7675, Leukocyte peroxidase test
   Limitation: 21 CFR 862.9 (c), (6) and (9)
   21 CFR § 866.2660, Microorganism differentiation and identification device,
   Limitation: 21 CFR 866.9 (c), (6) and (9)

2. Classification:

   Class II, Class I

3. Product code:

   JIO, LNW, JMT, JIR, LJX, MJM respectively

4. Panel:

   75, Chemistry and 83, Microbiology

H. Intended Use:

1. Intended use(s):

   See indications for use

2. Indication(s) for use:

   FemLab is a biochemical assay intended for use as a screening test for nitrites, blood, protein, leukocytes and proline-iminopeptidase in vaginal fluid samples. It is indicated for use as an aid in the presumptive diagnosis of vaginitis or urethritis and should be used in conjunction with laboratory tests such as Gram stain, microscopic examination, culture and KOH test. The FemLab Vaginitis Test Kit is for professional and laboratory use only.

3. Special conditions for use statement(s):

   For professional use only and used as a screening test.

4. Special instrument requirements:

   N/A

I. Device Description:

The FemLab Pro test kit has a total of seven sample application zones on the plastic test platform. The seven test zones are individual chemical and biological tests that screen for specific chemical or biological aspects of the vaginal fluid samples. Vaginal fluid is collected in a three-step collection procedure; two samples are used directly on test zones and the third is diluted in a custom designed buffer dilution and delivery system. The results are determined by observing color changes on each test zone following application.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   QuickVue Advance pH and Amines Test and QuickVue Advance G. Vaginalise Test.

2. Predicate 510(k) number(s):

   k040008 and k964015, respectively

3. Comparison with predicate:

   The device is similar to the predicate devices in the following ways: they have the same intended use and sensitivity, use the same clinical sample.
   The differences between the tests are: the proposed test is read in three minutes after application of the sample for pH while the predicate test is read two minutes after application, the proposed test device uses a filter membrane the predicates use a film membrane.

K. Standard/Guidance Document Referenced (if applicable):

None referenced

L. Test Principle:

The FemLab Vaginitis is a hand-held cassette with seven test zones that contain chemical or biological indicators that change color when in contact with vaginal fluid. It detects vaginal pH $\geq$ 4.7, proline iminopeptidase enzyme at concentrations of $\geq$ 20 pm/m, nitrite at concentrations $\geq$ 0.06 mg/dL, blood at concentrations of $\geq$0.015 mg/dL, protein at concentrations of $\geq$1.5 mg/dL and leukocyte at concentrations of $\geq$ 5 cells/h. Three sterile swabs are used to collect the vaginal sample. The pH test is run by gently rubbing one of the sterile swabs over the entire surface of test zone 1. The proline-iminopeptidase test zones (2a and 2b) are run second using the second of the three swabs. The third swab is combined with a buffer solution in a fluid specimen container. The container is open and the swab is mixed vigorously with the buffer for 15 seconds. Expunge as much liquid as possible from the swab by pressing and rotating the fiber portion against the wall of the container. The tip and cap are screwed onto the container and the container is then shaken up and down 10 times to ensure sample mixing. Finally, one drop of this mixture is dropped onto each of the remaining test zones (3-6). A color change indicates a positive result. No color change is a negative result.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Reproducibility testing was conducted by two operators, on three lots, for 30 days with blinded samples of varying activity. A total of 420 samples were tested with no discordant results for proline-iminopeptidase, blood, protein and leukocytes. The pH and Nitrite each had 2 discordant results they were recorded as borderline.

b. Linearity/assay reportable range:

Not applicable. The test is intended for qualitative use.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Real time stability testing has been conducted. Protocols and acceptance criteria were described and found to be acceptable. The stability is listed below:

When stored at 15 - 38ºC product is good until expiration date which is 12 months.

d. Detection limit:

Limits of detection were determined by prepared solutions spanning negative through borderline and threshold through positive. Nine (9) replicates of each level were evaluated using three different lots of the FemLab test kit. Data is represented here qualitatively.

Limits of Detection: FemLab pH Study						
	Lot A		Lot B		Lot C	
Solution Level	Correct call	% Correct	Correct call	% Correct	Correct call	% Correct
2.0	Neg	100%	Neg	100%	Neg	100%
2.5	Neg	100%	Neg	100%	Neg	100%
3.2	Neg	100%	Neg	100%	Neg	100%
3.7	Neg	100%	Neg	100%	Neg	100%
4.2	Neg	100%	Neg	100%	Pos	95.8%
4.7	Pos	100%	Pos	100%	Pos	100%
5.2	Pos	100%	Pos	100%	Pos	100%
5.7	Pos	100%	Pos	100%	Pos	100%

Limits of Detection: FemLab proline-iminopeptidase (pm/m)						
	Lot A		Lot B		Lot C	
Solution Level	Correct call	% Correct	Correct call	% Correct	Correct call	% Correct
0	Neg	100%	Neg	100%	Neg	100%
10	Neg	100%	Neg	100%	Neg	100%
20	Pos	100%	Pos	100%	Pos	95.8%
30	Pos	100%	Pos	100%	Pos	100%
40	Pos	100%	Pos	100%	Pos	100%
50	Pos	100%	Pos	100%	Pos	100%
60	Pos	100%	Pos	100%	Pos	100%
70	Pos	100%	Pos	100%	Pos	100%

Limits of Detection: FemLab Nitrite (mg/dL)						
	Lot A		Lot B		Lot C	
Solution Level	Correct call	% Correct	Correct call	% Correct	Correct call	% Correct
0.04	Neg	100%	Neg	100%	Neg	100%
0.05	Neg	100%	Neg	95.8%	Neg	100%
0.06	Pos	100%	Pos	100%	Pos	100%
0.10	Pos	100%	Pos	100%	Pos	100%
0.20	Pos	100%	Pos	100%	Pos	100%
0.30	Pos	100%	Pos	100%	Pos	100%
0.40	Pos	100%	Pos	100%	Pos	100%
0.50	Pos	100%	Pos	100%	Pos	100%

Limits of Detection: FemLab Blood (mg/dL)						
	Lot A		Lot B		Lot C	
Solution Level	Correct call	% Correct	Correct call	% Correct	Correct call	% Correct
0.005	Neg	100%	Neg	100%	Neg	100%
0.010	Neg	100%	Neg	100%	Neg	100%
0.015	Pos	100%	Pos	100%	Pos	100%
0.06	Pos	100%	Pos	100%	Pos	100%
0.08	Pos	100%	Pos	100%	Pos	100%
0.10	Pos	100%	Pos	100%	Pos	100%
0.12	Pos	100%	Pos	100%	Pos	100%
0.14	Pos	100%	Pos	100%	Pos	100%

Limits of Detection: FemLab Protein (mg/dL)						
	Lot A		Lot B		Lot C	
Solution Level	Correct call	% Correct	Correct call	% Correct	Correct call	% Correct
1.00	Neg	100%	Neg	100%	Neg	100%
1.4	Neg	100%	Neg	100%	Neg	100%
1.5	Pos	100%	Pos	100%	Pos	100%
1.7	Pos	100%	Pos	100%	Pos	100%
2.00	Pos	100%	Pos	100%	Pos	100%
3.0	Pos	100%	Pos	100%	Pos	100%
4.00	Pos	100%	Pos	100%	Pos	100%
5.00	Pos	100%	Pos	100%	Pos	100%

Limits of Detection: FemLab Leukocyte (cells/h)						
	Lot A		Lot B		Lot C	
Solution Level	Correct call	% Correct	Correct call	% Correct	Correct call	% Correct
0	Neg	100%	Neg	100%	Neg	100%
0-5	Neg	100%	Neg	100%	Neg	100%
5-15	Pos	100%	Pos	100%	Neg	100%
30	Pos	100%	Pos	100%	Pos	100%
60	Pos	100%	Pos	100%	Pos	100%
120	Pos	100%	Pos	100%	Pos	100%
240	Pos	100%	Pos	100%	Pos	100%
480	Pos	100%	Pos	100%	Pos	100%

Based on the above results the following sensitivity limits were chosen:

pH	above 4.7
Proline-iminopeptidase	20 pm/m
Nitrite	0.06-0.1 mg/dL
Blood	0.015-0.062 mg/dL
Protein	1.5-30 mg/dL
Leukocyte	5-15 cells/h

e. Analytical specificity:

To test the specificity of the FemLab test kit a variety of over-the-counter vaginal-use products as well as other compounds were tested for their ability to interfere with the tests. Normal (negative) vaginal fluid specimens as well as positive control samples were spiked with various concentrations of the product. None of the products tested at the concentrations indicated interfered with the detection of positives or negative samples.

Acetaminophen	20 mg/dL
Atropine	20 mg/dL
Caffeine	20 mg/dL
NaCl	20 mg/dL
Glucose	20 mg/dL
Penicillin	40,000 IU/mL
Iodine Potassium Decolorized Iodine Tincture	20 mg/dL
Disposable Douche	20 mg/dL
Spermicide	20 mg/dL

Cross–reactivity studies were performed using the FemLab test kit. The following organisms were tested ten times, 5 with a positive vaginal fluid sample and 5 with a negative sample. The results showed no cross-reactivity with the organisms listed.

Staphylococcus Aureus
Lactobacillus spp.
Group B Streptococcus

f. Assay cut-off:

See Detection Limit section above

2. <u>Comparison studies:</u>

a. Method comparison with predicate device:

Not performed; device was compared to clinically based standard criteria (see below).

b. Matrix comparison:

Not applicable

3. Clinical studies:

   a. Clinical Sensitivity:

   A multi-center study established the clinical performance of the device. A total of 300 vaginal fluid samples were collected post-pubertal women. Vaginal fluid samples were collected first for the FemLab test and handed to one technician, and then a second set of samples were taken and handed to a second technician who performed the traditional lab test.

   For a patient to be consider positive by traditional laboratory methods a positive result needed to be recorded from a commercially available pH and proline-iminopeptidase test, wet mount microscopic evaluation and culture system for detection of vaginitis or urethritis. To be considered positive by FemLab test kit in the clinical studies described below, the patient had to have a positive result(s) from the following: pH, proline-iminopeptidase, nitrite, blood, protein and Leukocyte.

   Of the 300 specimens, 266 patients were negative and 18 were positive by the traditional methods. The table below presents a comparison of the FemLab test kit to the traditional method:

   Healthy vs. Vaginitis

Comparative Method		Traditional Laboratory Method	
	Outcome	Positive	Negative
FemLab Test Kit	Positive	18	9
	Negative	7	266

   Overall agreement is – 94.6%

   c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off**:**

   See detection limits above

5. Expected values/Reference range:

   Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

P. Other Supportive Device and Instrument Information:

Q. Administrative Information:

1. Applicant contact information:

   a. Name of applicant:

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2. Review documentation:

R. Reviewer Name and Signature:

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